

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FERA PHARMACEUTICALS, LLC,

Plaintiffs,

v.

AKORN, INC.; SEAN BRYNJELSEN; and
MICHAEL STEHN,

Defendants.

Case No. 12-cv-07694-LLS

AMENDED COMPLAINT

INTRODUCTION

1. Fera Pharmaceuticals, LLC, (“Fera”) is a marketer, distributor, and provider of sterile anti-infective ophthalmic drugs. Fera’s business model is to realize opportunities via acquisitions, in-licensing, developing and marketing new drug applications (“NDA”) and abbreviated new drug applications (“ANDA”).

2. On July 13, 2009, acquired all rights, title and interest in seven sterile anti-infective ophthalmic drugs previously owned and marketed by Fougera, a division of Nycomed US Inc. The products included Bacitracin; Bacitracin Zinc and Polymyxin B Sulfate; Gentamicin Sulfate; Neomycin and Polymyxin B Sulfates and Bacitracin Zinc; Neomycin and Polymyxin B Sulfates and Dexamethasone; Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Acetate; and Erythromycin Ophthalmic Ointments USP (“Erythromycin” and collectively the “Fera Products”).

3. In early 2009, Fera and Akorn Inc. (“Akorn”) entered into discussion to have Akorn manufacture all Fera Products. On February 23, 2009, in order to facilitate the exchange of confidential information and trade secrets by Fera to Akorn Inc. (“Akorn”) for the purposes of

manufacturing Fera Products the parties entered into a Confidentiality and Non-Disclosure Agreement (“CDA Agreement” or “CDA”).

4. Between February 23, 2009 and July 13, 2009, Akorn made misrepresentations and omitted information concerning Akorn’s desire, equipment, and capacity to manufacture Fera Products.

5. Based upon the misrepresentations made by Akorn, on July 13, 2009, Fera and Akorn signed and duly executed a commercial manufacturing supply agreement (“CMS Agreement” or “CMS”), whereby Akorn agreed to manufacture and supply Fera Products.

6. Akorn failed to manufacture Fera Products as set forth in the CMS causing Fera delays in bringing its products to market. In addition, through technical transfers of data, Fera provided Akorn, at Akorn’s request, highly sensitive confidential and proprietary information and trade secrets in order to facilitate the manufacturing of Fera Products. Akorn wrongfully utilized Fera’s trade secrets in order to produce Erythromycin 1 gram (“Erythromycin 1g”) and Erythromycin 3.5 gram (“Erythromycin 3.5g”) for itself, in unfair competition with Fera. Additionally, Akorn has acquired the technical and manufacturing knowledge to produce other Fera Products such as Bacitracin and has taken steps evidencing a desire to manufacture Bacitracin in violation of the CDA and CMS.

7. All of the foregoing acts are in violation of the CDA and CMS and have caused Fera substantial harm, including but not limited to, lost profits, lost market share, competitive disadvantage, production delays, devaluation of Fera’s intellectual property, loss of an exclusive commercial advantage through misappropriation of trade secrets, and additional costs and expenses in order to cover and produce Fera Products through other means.

8. Accordingly, Plaintiff seeks an award of equitable and monetary relief in the form of a declaratory judgment holding that the information provided to Akorn is a trade secret and governed by both the CDA Agreement and the CMS Agreement, injunctive relief to restrain Akorn from selling Erythromycin and any other Fera Product pursuant to the CDA and CMS, and an award of damages, including punitive damages, costs, and attorneys' fees for Defendant's willful and deceptive practices that have deprived Plaintiff the fruits of its commercial advantages in the ophthalmic ointment market and devalued Fera's intellectual property assets.

9. Plaintiff Fera Pharmaceuticals, LLC is a limited liability company licensed in New York and having a principal place of business at 134 Birch Hill Road, Locust Valley, New York 11560.

10. Defendant Akorn, Inc. is a Louisiana corporation with its principal place of business at 1925 West Field Court, Lake Forest, Illinois 60045.

11. Non-party Mark Silverberg is a resident of Illinois, upon information and belief. During the relevant time period, Silverberg was employed by Akorn and served as Akorn's executive vice-president of operations, global quality assurance & technical services.

12. Defendant Sean Brynjelsen is a resident of Illinois, upon information and belief. During the relevant time period, Defendant Brynjelsen was employed by Akorn and served as Akorn's director of business development and contract manufacturing.

13. Defendant Michael Stehn is a resident of New Jersey, upon information and belief. During the relevant time period, Defendant Stehn was employed by Akorn and served as Akorn's senior vice president of operations.

14. Jurisdiction is established by the removal of this matter from the Supreme Court of the State of New York, County of New York to the United States District Court for the Southern District of New York pursuant to 28 U.S.C. § 1332 and 1441.

FACTUAL BACKGROUND

The CDA Agreement

15. In the spring of 2009. The parties began negotiating to have Akorn manufacture Fera Products for Plaintiff. At that time the parties agreed to keep all information, trade secrets, and marketing plans, among other categories exchanged “whether written or oral” confidential. (CDA Agreement attached hereto as Exhibit A (“Ex.”), pg. 1, Section 1). Akorn agreed to hold and “to maintain in strict confidence all Confidential Material” exchanged by the parties. Ex. A, pg. 2, Section 3.

16. Under section 8,

Akorn and Fera each hereby agree that any breach of this Agreement may result in irreparable injury and damage that may not be adequately compensable in money damages, and which may have no adequate remedy at law, and therefore each of Akorn and Fera consents and agrees that either party may seek injunctions, orders or decrees as may be necessary to protect its Confidential Material..

Ex. A.

17. The CDA is to be “construed in accordance with and controlled by the laws of the State of Illinois...” Ex. A, pg. 3, Sec. 13.

18. On or approximately about June 9, 2009, Fera provided Akorn with a slideshow presentation of Fera’s marketing plans, its market share projections, and annual forecasting needs for each Fera Product, information concerning current and projected market shortfalls for Fera Products.

19. On June 17, 2009, Frank DellaFera, President of Fera, scheduled a meeting between 1:00 p.m. and 3:00 p.m. with Sean Brynjelsen and Michael Stehn as recorded in an email from Sean Brynjelsen dated June 2, 2009. The purpose of the meeting was to discuss:

- 1) Ointment Products
- 2) Manufacturing
- 3) Forecast / Capacity
- 4) Project deliverables and timing
- 5) Business Discussion

(Email, From: Sean Brynjelsen, (June 2, 2009).

20. At the meeting on June 17, 2009, Sean Brynjelsen and Michael Stehn intentionally or with gross recklessness falsely represented to Frank DellaFera that Akorn had the manufacturing capacity, equipment, ability, and intent to meet Fera's projected Fera Products forecasts through at least 2010 and that there were no anticipated developments that would reduce or otherwise impede Akorn's manufacturing capacity. Sean Brynjelsen's and Michael Stehn's statements were false when made because Akorn knew at the time the statements were made that Akorn did not have had such manufacturing capacity, equipment, ability, or intent to manufacture Fera Products and instead desired Fera's trade secrets, confidential information, market share plans, and product information in order to manufacture Fera Products for themselves.

21. On June 23, 2009, Frank DellaFera, again met with Sean Brynjelsen and others employed by Akorn. At the meeting, Sean Brynjelsen intentionally or with gross recklessness repeated the prior false representations made to Frank DellaFera on June 17, 2009. Also discussed at the meeting was the pricing of Fera Products that Akorn represented that it had the manufacturing capacity, equipment, ability, and intent to meet Fera's projected Fera Products forecasts through at least 2010.

The CMS Agreement

22. In reliance upon the Defendants' false representations made in ¶ 18-21, Plaintiff was under the false impression that Akorn had the desire, capacity, experience, and equipment necessary to manufacture Fera Products and entered into the CMS Agreement.

23. On July 13, 2009, Fera was induced into agreeing to allow Akorn to manufacture Fera Products either exclusively or semi-exclusively for seven years based on the below table. (CMS Agreement attached hereto as Ex. B); *See* Ex. B, pg. 3, Section 2¹, Ex. B, pg. 14, Section 12(a), Ex. B, Ex. B (Exclusivity Table)).

Fera Products			
Product	Unit	Price	Exclusivity
Neo-Poly-Dex	3.5 gram tube	\$2.99/tube	Exclusive
Baci-Poly	3.5 gram tube	\$2.99/tube	Semi-exclusive
Neo-Poly-Baci	3.5 gram tube	\$1.99/tube	Semi-exclusive
Gentamicin Ointment	3.5 gram tube	\$3.25/tube	Semi-exclusive
Bacitracin Ointment	3.5 gram tube	\$1.99/tube	Exclusive
Neo-Poly-Bac-HC Ointment	3.5 gram tube	\$3.25/tube	Exclusive
Erythromycin Ointment	3.5 gram tube	\$1.75/tube	Exclusive
Erythromycin Ointment	1 gram tube x50	TBD	Exclusive

24. While the above-referenced table identified Erythromycin 3.5g as exclusive, a note below the table provides that:

Erythromycin 3.5 gram is Exclusive if based on Fera Pharmaceuticals approved regulatory filing. Akorn agrees not to utilize information contained in the Fera Pharmaceuticals regulatory filing for purposes of manufacturing said product including API source. However, nothing in this agreement prevents Akorn from using their *existing* FDA approval to manufacture, sell and distribute Erythromycin 3.5 gram.

¹ Under the CMS, "Exclusive" means manufacturing of specified product(s) as identified in Exhibit A solely for Customer over the duration of this agreement. Ex. B., pg. 2, Section 1(h). "Semi-Exclusive" means manufacturing of specified product(s) identified in Exhibit B of the CMS solely for Fera and Akorn over the duration of the CMS. Ex. B., pg. 2, Section 1(t).

Id. (emphasis added).

25. On a date known only to Defendants, but prior to the signing of the CMS, Akorn discontinued and withdrew its FDA application for Erythromycin 3.5g. According to the CMS Agreement, once Akorn withdrew its Erythromycin 3.5g, Akorn was required to produce Erythromycin 3.5g on an exclusive basis for Fera because it no longer had “existing FDA approval.” *Id.*

26. The CMS also required Akorn to prioritize the production of Fera Products over Akorn’s products. *See* Ex. B, pg. 5, Section 4(b).

27. Furthermore, and in addition to and without limiting the obligations and rights of the parties under the existing CDA Agreement, the CMS Agreement also prohibits the improper use or disclosure of confidential information,

During the Term, including any extension thereof, and for a period of five (5) years thereafter, the Parties shall not disclose, communicate or otherwise make available to any third party, and shall not use or deal with in any manner (except as permitted by this Agreement) any Confidential Information of the other Party, nor shall a Party utilize Intellectual Property Rights disclosed in any patent of either Party, other than as required to manufacture or supply a Product or any other purpose as may be required for the Parties to perform its respective obligations under this Agreement; provided, however, for any Confidential Information that constitutes a trade secret of a Party shall continue for as long as the same remains a trade secret of that Party notwithstanding any limitation or exceptions provided herein.

Id. at pg. 13, Section 11(b).²

28. The CMS Agreement states that remedies due to a breach of contract through the misuse of confidential information constitutes “irreparable harm,” and the harmed party “may

² “‘Confidential Information’...means any and all information, trade secrets and know-how of or data about each of the Parties, their clients, or their operations and other matters of a confidential or proprietary nature, including, without limitation, a Product and its Specifications...” *Id.*, at pg. 12, Section 11(a).

specifically enforce the obligations of the other under this paragraph, by injunction or otherwise, in addition to and not in limitation of any other remedies that a Party may have at law or in equity.” *Id.*, at pg. 13, Section 11(e).

29. The CMS is to be “construed and enforced according to the laws of the State of New York.” Ex. A, pg. 17, Sec. 22.

Akorn Fails to Perform Under the CMS Agreement

30. Almost immediately upon executing the CMS, Akorn failed to perform its duties with respect to manufacturing the Fera Products. After signing the CMS, Akorn sought to acquire Fera’s trade secrets in order to manufacture Erythromycin and Bacitracin for itself under the guise of seeking information to manufacture Fera Products.

31. Mark M. Silverberg, executive vice-president of operations, global quality assurance & technical services, wrote to Frank DellaFera, the co-founder of Fera, that Akorn “really need[s] immediate access to the following:

- Product ANDAs
- Product master batch records
- Raw material and product specifications
- Respective tech packages,
- Packaging sample for the Erythromycin 1 gram commercial pack (the 50 pack)
- Estimated quarterly forecast for each product SKU (starting with 4Q 2009) for the next four quarters.”

(Email, From: Mark Silverberg (Jul. 27, 2009)).

32. Product ANDAs are not typically transferred from drug developer to drug manufacturer.

33. On July 31, 2009, Fera sent Akorn a purchase order (“PO”) for four products: Erythromycin 3.5g, Bacitracin, Gentamicin, and Neo-Poly-Baci.

34. In August 2009, at Akorn's request, Fera provided Akorn with confidential information regarding the active product ingredient ("API") for Erythromycin.

35. Thereafter, Akorn breached the CMS Agreement in several ways. According to the CMS, Akorn was responsible for ordering raw materials and putting in place material specifications. *See* Ex. C of the CMS attached as Exhibit B. However, Akorn improperly required Fera to procure and pay for the raw materials for Bacitracin. (Email, From: Frank DellaFera (Aug. 6, 2009)). In addition, Akorn improperly required Fera commit to a risk authorization for the erythromycin tube purchases, and also had Fera pay for filter validations, both violations of Akorn's obligations under the CMS. In mid-August 2009, Akorn required Fera to purchase a refrigerator for Akorn in order to store the API. Akorn then refused to acquire the necessary equipment to manufacture Fera Products.

36. On September 11, 2009, Fera inquired as to the status of the four Fera Products that that were part of the PO's sent on July 31, 2009. Akorn failed to provide assurances that the Fera Products would be produced and failed to fill the POs.

37. On September 16, 2009, Fera notified Akorn that the FDA had approved an expedited and confidential method for approval of their Erythromycin and Bacitracin products. Fera worked with the FDA to develop an expedited process to bring Erythromycin and Bacitracin to market because there were market shortages of these products at the time ("Fera's FDA Process"). Fera's FDA Process was Fera's proprietary trade secret information that provided Fera a competitive advantage in bringing products to market faster than other drug manufacturers.

38. On September 17, 2009, one day after Fera received FDA approval to sell Erythromycin and Bacitracin through the FDA's expedited approval pathway, Akorn notified

Fera that it planned to breach the CMS Agreement because, based upon Akorn's forecasts, Akorn did not have sufficient capacity to manufacture Fera Products. (Email, From: Sean Brynjelsen (Sept. 17, 2009)). Akorn told Fera that the company should make "alternative supply arrangements." *Id.*

39. On September 28, 2009, Fera established alternative supply arrangements with a third party manufacturer ("Third Party Manufacturer") to manufacture Erythromycin, thereby causing Fera to incur additional costs to cover for Akorn's breach.

40. On November 16, 2009, Fera established alternative supply arrangements with the Third Party Manufacturer to manufacture Gentamicin, thereby causing Fera to incur additional costs to cover for Akorn's breach.

41. On December 7, 2009, Sean Brynjelsen informed Fera that additional POs would not be accepted for 2010. (Email, From: Sean Brynjelsen (Dec. 7, 2009)). Akorn acknowledged that it would only honor the open orders of Bacitracin and Erythromycin, and refused to manufacture the Gentamicin and Neo-Poly-Baci POs previously submitted, in violation of the CMS Agreement's priority provision and Akorn's obligation to fill timely submitted POs. Akorn was the only manufacturer of Gentamicin at the time, and knowingly entered into the CMS and immediately breached the agreement to delay Fera from entering into the market.

42. On December 10, 2009, Fera informed Akorn that the company was "very concerned" with Akorn's capacity issues and its refusal to produce Fera Products. (Email, From: Sean Brynjelsen (Dec. 7, 2009)). Fera was perplexed by Akorn's inability to fill its orders, because Fera had provided Akorn with detailed proprietary annual forecasts for 2009 and 2010 for Fera's Products prior to signing the CMS and chose to partner with Akron in reliance upon Akorn's representations concerning its capacity, equipment, and ability to manufacture Fera

Products. (Fera Quarterly Forecast). As detailed in ¶ 18-21, Fera had received several confirmations from Akorn's Vice President and General Manager, Michael Stehn, and Sean Brynjelsen in June 2009, during the negotiations on the CMS Agreement that Akorn had the capacity and the ability to manufacture Fera Products in the amounts stated in Fera's annual forecasts.

43. On December 30, 2009, Fera executed a supply contract with the Third Party Manufacturer to manufacture Bacitracin due to Akorn's alleged capacity issues and its refusal to provide assurances or guarantees that it would meet Fera's 2010 production requirements.

44. Prior to the signing of the CMS Agreement, Sean Brynjelsen had wrote to Fera that "in the event that our vendors drastically increase prices on us" we would invoke the material change clause and "[i]f it was ever invoked the clause requires Akorn to provide proof of material costs anyways." (Email, From: Sean Brynjelsen, (April 3, 2009)). Akorn never provided any proof of material cost increases.

45. Beginning in November 2009, Akorn increased the price to manufacture Bacitracin from \$1.99 to \$3.00, a 51% increase (later Akorn would again raise the price by nearly another \$.95, an additional 33% increase, again without justification and in violation of the CMS Agreement). While the CMS Agreement provides for price increases as a result of material increases of manufacturing costs, Akorn unilaterally modified the price to manufacture Bacitracin in violation of the CMS without justification or proof that there were any material increases in the manufacturing cost. Below is an estimated list of the orders that were charged in violation of the CMS Agreement.

Bacitracin Over Charges					
Date	Sales Price	Quantity	Akorn Charges	CMS Price	Damages
11/11/2009	\$ 3.00	98,000	\$ 294,000	1.99	\$ 98,980
1/11/2010	\$ 3.00	98,000	\$ 294,000	1.99	\$ 98,980
2/25/2010	\$ 3.00	98,000	\$ 294,000	1.99	\$ 98,980
4/6/2010	\$ 2.84	49,000	\$ 139,160	1.99	\$ 41,650
5/7/2010	\$ 2.84	49,000	\$ 139,160	1.99	\$ 41,650
10/19/2010	\$ 2.84	49,000	\$ 139,160	1.99	\$ 41,650
10/20/2010	\$ 2.84	98,000	\$ 278,320	1.99	\$ 83,300
3/31/2011	\$ 3.95	49,000	\$ 193,550	1.99	\$ 96,040
4/4/2011	\$ 3.95	147,000	\$ 580,650	1.99	\$ 288,120
10/4/2011	\$ 3.95	147,000	\$ 580,650	1.99	\$ 288,120
Grand Total		882,000	\$ 2,932,650		\$ 1,177,470³

Akorn Uses Fera's Confidential Information to Re-Launch Erythromycin Products

46. On April 20, 2010, Akorn announced that the FDA approved Akorn's request to re-launch the sale of Erythromycin 3.5 g. (Akorn April 20, 2010, Press Release). The Press Release stated that "[t]he company intends to begin shipping the product immediately." *Id.* The Press Release stated further:

Raj Rai, the Interim Chief Executive Officer of Akorn stated, "We identified an opportunity to re-launch Erythromycin as ongoing market shortages have made this an attractive product which is complimentary to the other ophthalmic ointments Akorn currently sells."

According to IMS Health, the annualized U.S. sales for Erythromycin 3.5 g based on fourth quarter 2009 data, were approximately \$26 million.

Id.

47. Akorn wrongfully used Fera's trade secrets, acquired Fera's API source, utilized Fera's expedited FDA Approval pathway, obtained Fera's annual forecasting, and obtained

³ All damage figures and calculations are subject to change and review upon completion of discovery that is anticipated to yield additional damages caused by Akorn's conduct.

Fera's marketing plans and strategy to unfairly usurp Fera's business opportunity to sell Erythromycin.

48. On April 22, 2010, Sean Brynjelsen notified Fera that Akorn was planning on implementing a second shift in the Somerset, New Jersey, Akorn's sterile Opht ointment manufacturing facility, in order to alleviate capacity issues. However, whatever additional capacity was added at Akorn, upon information and belief, went towards wrongfully producing additional Akorn-labeled Erythromycin and not towards manufacturing Fera Products, in violation of the exclusivity and priority requirements under the CMS.

49. On May 14, 2010, Fera entered into agreements with the Third Party Manufacturer to supply the remaining Fera Products: Neo-Poly-Baci, Neo-Poly-Dex, Neo-Poly-Bac-HC, and Baci-Poly. For each product that Fera entered into an agreement with the Third Party Manufacturer to produce, Fera paid \$50,000 for technical transfers, and in total paid \$350,000 in additional costs to cover Akorn's breach of the CMS Agreement.

50. On September 16, 2010, Akorn announced in a press release that the FDA approved Akorn's request to sell Erythromycin 1g. The press release stated:

Erythromycin Ophthalmic Ointment USP 1 g as a supplement to the Company's already approved Abbreviated New Drug Application (ANDA) for Erythromycin Ophthalmic Ointment USP 3.5 g. The company has begun shipping the product to its customers.

Raj Rai, Chief Executive Officer of Akorn stated, "Recent market shortages have made this an attractive product which is complimentary to the other ophthalmic ointments Akorn currently sells. This approval gives us access to both the sizes of Erythromycin Ophthalmic Ointment and positions us to compete effectively in all channels through which the product is sold." According to IMS Health, the annualized U.S. sales for Erythromycin 1g based on second quarter 2010 data were approximately \$23 million.

(Akorn September 16, 2010, Press Release).

51. As of September 2010, the Erythromycin market for both the 1g and 3.5g was estimated by Akorn to be \$49,000,000 annually.

52. On March 31, 2011, Akorn “[j]ust wanted to give [Fera] a heads up that we are considering exiting the contract business at the end of this year.” (Email, From: Sean Brynjelsen (Mar. 31, 2011)). This statement clearly indicated Akorn’s violation of the CMS by prioritizing the manufacturing of its own products over the manufacturing of Fera’s Products.

53. As Akorn explained in its 2011 Annual Report filed with the Securities and Exchange Commission (“SEC”), “[t]he decrease in contract services revenue was due to refocusing our manufacturing plants on producing Akorn-labeled products...” *See* Akorn 2011 Annual Report, pg. 22.

**Akorn’s Violation of the CDA and CMS Agreements Caused
Fera Substantial Harm**

54. Akorn improperly utilized Fera’s confidential information, obtained Fera’s marketing and forecasting projections, obtained FDA approval utilizing Fera’s FDA Process and gave priority to its own label products over Fera’s in violation of both the CDA and CMS Agreements as provided generally under the CDA and as provided under the confidentiality provisions in Section 11 of the CMS.

55. According to IMS National Sales Perspective (NSP), an organization that tracks the market share and total market for pharmaceutical products, from February 2010 through February 2011 the total market share for Erythromycin 3.5g was \$31,563,110 and for 1g was \$27,863,088, which equals a total of \$59,426,198. From February 2011 through February 2012, the total market for Erythromycin 3.5g was \$33,572,033 and for 1g was \$28,399,309, which equals a total of \$61,971,342.

56. In 2009, Fera provided Akorn with its business plan to acquire a 40% market share of the Erythromycin market in order to satisfy shortages of Erythromycin in the marketplace. (Market Share Analysis). Accordingly, when Akorn began selling its Erythromycin in competition with Fera, not only was Fera's market share negatively impacted, but the market for Erythromycin experienced a price compression from Akorn's wrongfully acquired market share. As a result, Fera has been deprived of approximately \$16,471,040 in revenues in 2011, \$19,784,554 in revenues in 2012, and Fera's estimated 2013 revenues (through February 2013) for its Erythromycin products is estimated to be \$20,631,899 for an approximate total, subject to revision, of \$56,887,493 in damages stemming from Akorn's wrongful sales of Erythromycin and the ensuing price compression.⁴

57. According to IMS NSP, Akorn's sales of Erythromycin in 2011 were \$6,276,750, and in 2012 were \$15,569,824 for a total of \$21,846,574. Akorn's sales of Erythromycin were in unfair competition with Fera.

58. Akorn improperly utilized the confidential information Fera provided to Akorn, in violation of the CDA and CMS Agreements, in order to usurp Fera's business advantage, prevent and delay Fera from entering the market and selling Fera Products.

59. Throughout the rest of 2011, Akorn continued to manufacture only Bacitracin on behalf of Fera. In January 2012, Akorn attempted to renegotiate the CMS Agreement. On February 2, 2012, Akorn proposed altering Exhibit A to the CMS agreement and making

⁴ The foregoing damage calculation was derived from the actual market size for each Erythromycin product, an estimated 40% market share that Fera's projections indicated it would have enjoyed but for Akorn's wrongful use of Fera's confidential information, plus the size of the market for Erythromycin absent the observed price compression taken from the initially planned retail pricing for each product less the actually observed selling price for each product, less the amount and actual market share of Erythromycin Fera actually sold and held in each year.

Bacitracin a non-exclusive product. (Email, From: Sean Brynjelsen, (Feb. 2, 2012)). However, since Akorn had never been able to successfully formulate Bacitracin prior to Fera's technical transfer, Akorn's contractual proposal was a thinly disguised attempt to obtain the know-how to manufacture Bacitracin by leveraging Akorn's experience in manufacturing Bacitracin for Fera. (Email, From: Sean Brynjelsen (Jul. 20, 2009)). Sean Brynjelsen, Akorn's director of contract services, wrote: "[p]rior attempt to develop Bacitracin at Somerset [Akorn's Office] was unsuccessful.").

Akorn Improperly Terminates the CMS Agreement

60. On May 1, 2012, Akorn further breached the CMS Agreement by wrongfully terminating production of Bacitracin. Akorn wrongfully claimed that the termination was in accordance with Sections 12(b), 12(e), and 17 of the CMS. Section 12(b) of the CMS Agreement provides that Akorn may terminate the agreement if "Customer fail [sic] to fulfill the minimum annual quantity purchases for any one calendar year period as set forth in Exhibit D." Ex. B, pg. 14. Turning to Exhibit D of the CMS, the agreement makes it clear that the minimum purchase quantities must be purchased within the contract year defined as "that twelve month period beginning with the Effective Date or an anniversary of the Effective Date." *Id.*, at Ex. D. Accordingly it was not possible for Fera to be in breach of the CMS' minimum purchase requirements because the contract year would not expire until July 13, 2012.

61. On May 4, 2012, Fera's counsel wrote Akorn disagreeing with Akorn's basis for termination. Fera also requested that Akorn confirm in writing that it would abide by Section 11 of the CMS agreement and maintain all confidential information secret. On May 9, 2012, Akorn confirmed that it would continue to comply with Section 11.

62. From May 2012 through September 2012, Akorn and Fera entered into good faith negotiations as described in Section 14(a)(i) of the CMS Agreement. Ex. B, pg. 14.

63. In mid-June 2012, a pharmaceutical company (the “Acquiring Company”) approached Fera about acquiring all of Fera’s rights, title, and interest in Fera Products. After Fera agreed to acquisition in principal, the Acquiring Company conducted due diligence on Fera Products and discovered that Fera’s Bacitracin and Erythromycin confidential information had been transferred to Akorn. The Acquiring Company also discovered that Akorn was manufacturing Erythromycin without Fera’s permission, using Fera’s confidential and proprietary information and trade secrets, and that Akorn had confidential information regarding Fera’s Bacitracin product.

64. The Acquiring Company declined to follow through with the acquisition of Fera Products due to Akorn’s improper manufacturing of Erythromycin 3.5g and 1.g and Akorn’s use of Fera’s confidential and proprietary information and trade secrets, in violation of the CDA and CMS Agreements. Further, the Acquiring Company was concerned that Akorn would begin to use Fera’s confidential and proprietary information and trade secrets to manufacture Bacitracin.

65. As a result of Akorn’s violation of the CDA and CMS Agreements and use of confidential and proprietary information and trade secrets for Akorn’s own benefit, the value of Fera’s company overall, the value of Fera Products, and the value of Fera’s commercial advantages in the sterile anti-infective ophthalmic market has declined significantly and irreparably.

66. In late August 2012, Fera again reached out to Akorn to attempt to resolve the instant dispute via mediation in accordance with Section 14(a)(ii) of the CMS Agreement. *Id.*, pg. 15. After a brief telephone discussion, Akorn declined to mediate the instant dispute.

67. Akorn followed-up with a letter stating that Akorn had been relieved of “any obligations to mediate and arbitrate Fera’s claims and dispute.” (Letter, From: Akorn (Aug. 29, 2012)). On the same day, Fera responded to Akorn’s letter acknowledging that the “parties have waived any and all mediation and arbitration obligations under the [CMS]...” (Letter, From: Fera (Aug. 29, 2012)).

68. On September 5, 2012, the parties had a follow-up telephonic meeting whereby Akorn reiterated that it refused to mediate or arbitrate these disputes.

69. Due to the Akorn’s acts and conduct as described above, Plaintiff seeks an award of equitable and monetary relief in the form of a declaratory judgment, injunctive relief, and an award of damages, including punitive damages, costs, and attorneys’ fees for Defendant’s willful and deceptive practices that have deprived Plaintiff the fruits of its commercial advantages in the ophthalmic ointment market and devalued Fera’s intellectual property assets.

COUNT I:

(For Breach of Contract as to Defendant Akorn)

70. Plaintiff repeats, re-alleges, and incorporates ¶1-69 as set forth in full herein.

71. Defendant breached the CDA Agreement with Plaintiff and caused damages due to the acts as described above by:

- a. Violating the CDA by failing to hold secret marketing, forecasting, and other business plans that provided Fera with a commercial advantage.
- b. Violating the CDA by using technical information disclosed in confidence to Akorn in order to manufacture Fera Products. The specific unauthorized and violating uses of Fera’s Erythromycin confidential information and trade secrets for 3.5g and 1g include, but are not limited to:

- i. the API source,
- ii. marketing projections,
- iii. industry forecasts including market share and price projections,
- iv. Fera's FDA Process,
- v. manufacturing techniques and specifications, and
- vi. sterilization and formulation techniques, processes, and procedures.

Akorn's wrongful use of Fera's confidential information, together with the wrongful manufacturing and sales of products exclusive to Fera, constitute breaches of the CDA agreement and caused, and continue to cause, Fera an estimated \$56,887,493 in damages due to lost sales, decreased market share, and price compression.

- c. Due to Akorn's wrongful use of Fera Products, including Erythromycin and the potential use of other Fera Products, such as Bacitracin, Fera has been irreparably harmed through the devaluation of the company due to the loss of control of their trade secrets and the market's belief that Fera's trade secrets have been and will continue to be wrongfully utilized in the future. Fera's business valuation has declined significantly due to Akorn's breach of contract in an amount to be determined at trial.

72. Defendant breached the CMS Agreement with Plaintiff and caused damages due to the acts as described above by:

- a. Failing to manufacture Fera Products that were ordered in a timely manner pursuant to the CMS Agreement, thereby depriving Fera of the benefit of the bargained agreement and forcing Fera to expend unnecessary resources to

cover and procure alternate means to manufacture Fera Products causing damages in the amount of at least \$379,370.

- b. Raising the manufacturing cost of Bacitracin in violation of the CMS Agreement, thereby forcing Fera to pay nearly double the price negotiated per tube of Bacitracin without cause or justification. Fera made overpayments to Akorn in an amount totaling at least \$1,177,470.
- c. Violating the exclusivity provisions of the CMS Agreement by producing Erythromycin 3.5g and 1g in competition with Fera. The violation of the exclusivity provision caused, and continues to cause, Fera an estimated \$56,887,493 in damages due to lost sales, decreased market share, and price compression.
- d. Violating the priority provisions of the CMS Agreement by giving priority to Akorn's Erythromycin and other products instead of Fera's Erythromycin and Fera Products. Akorn's violation of the priority provision has caused, and continues to cause, Fera an estimated \$56,887,493 in damages due to lost sales, decreased market share, and price compression.
- e. Violating the confidentiality provision under the CMS by failing to hold secret technical information disclosed in confidence to Akorn in order to manufacture Fera Products. The specific unauthorized and violating uses of Fera's Erythromycin confidential information and trade secrets for 3.5g and 1g include, but are not limited to:
 - i. the API source,
 - ii. marketing projections,

- iii. industry forecasts including market share and price projections,
- iv. Fera's FDA Process,
- v. manufacturing techniques and specifications, and
- vi. sterilization and formulation techniques, processes, and procedures.

Akorn's wrongful use of Fera's confidential information, together with the wrongful manufacturing and sales of products exclusive to Fera, constitute breaches of the CMS agreement and caused, and continue to cause, Fera an estimated \$56,887,493 in damages due to lost sales, decreased market share, and price compression.

- f. Due to Akorn's wrongful use of Fera Products, including Erythromycin and the potential use of other Fera Products, such as Bacitracin, Fera has been irreparably harmed through the devaluation of the company due to the loss of control of their trade secrets and the market's belief that Fera's trade secrets have been and will continue to be wrongfully utilized in the future. Fera's business valuation has declined significantly due to Akorn's breach of contract in an amount to be determined at trial.
- g. Damages suffered as a result of Fera's acquisition of its own raw materials in violation of the CMS Agreement in an amount to be determined.
- h. Damages suffered as a result of Fera's purchase of a refrigerator for Akorn in order to store the API in violation of the CMS agreement when Akorn had represented that it had the ability and capacity to manufacture Fera Products when Akorn, in fact, did not.

- i. Damages as a result of Akorn's improper termination of the CMS agreement and refusal to manufacture Fera Products in order to improperly manufacture its own products in competition with Fera. Akorn's basis for termination was improper because it was Akorn who notified Fera that its supply requirements were too great for Akorn's capacities, going so far as to recommend alternative supply arrangements, and not, as falsely claimed, a failure on Fera's part to order sufficient minimum quantities under the CMS agreement.

73. Plaintiff is owed and requests relief for the aforementioned damages plus statutory interest, forum fees and costs, attorneys' fees, and any other relief as the Court may deem just and equitable.

COUNT II:

(For Unfair Competition as to Defendant Akorn)

74. Plaintiff repeats, re-alleges, and incorporates ¶1-73 as set forth in full herein.

75. As shown through the foregoing acts and conduct, Akorn engaged in unfair competition by misappropriating, in bad faith, Fera's confidential and proprietary information and trade secrets that led to the loss of a commercial advantage that belonged exclusively to Fera.

76. Plaintiff has shown damages through itemized calculation losses amounting to at least \$56,887,493, together with the loss of Fera's business valuation that is the difference between what a an acquirer would pay for Fera at market price and the actual price paid to acquire Fera due to the unfair competition in an amount to be determined at trial.

77. Alternatively, Akorn's wrongful profits for 2011 and 2012 in the amount of \$21,846,574, and any additional or unaccounted for wrongful profit should be disgorged and returned to Fera.

78. Plaintiff is owed and requests relief for the aforementioned damages plus statutory interest, forum fees and costs, attorneys' fees, punitive damages, and any other relief as the Court may deem just and equitable.

COUNT III:

(For Misappropriation of Trade Secrets as to Defendant Akorn)

79. Plaintiff repeats, re-alleges, and incorporates ¶1-78 as set forth in full herein.

80. As shown through the foregoing, Plaintiff possessed valuable trade secrets, some of which are described in ¶72(e), and Defendant used and is using those trade secrets in breach of an agreement, confidence, and duty, constituting improper means, to the harm and detriment of Plaintiff.

81. Plaintiff has shown damages through its calculations that losses amounting to at least \$56,887,493, together with the loss of Fera's business valuation that is the difference between what a an acquirer would pay for Fera at market price and the actual price paid to acquire Fera due to the misappropriation of Fera's trade secrets in an amount to be determined at trial.

82. Alternatively, Akorn's wrongful Erythromycin profits for 2011 and 2012 in the amount of \$21,846,574, and any additional or unaccounted for wrongful profits should be disgorged and returned to Fera.

83. Additionally, Plaintiff seeks to enjoin Akorn from further use, disclosure and any other wrongful utilization of Fera's trade secrets.

84. Plaintiff is owed and requests relief for the aforementioned damages plus statutory interest, forum fees and costs, attorneys' fees, punitive damages, and any other relief as the Court may deem just and equitable.

COUNT IV:

(For Fraud in the Inducement as to All Defendants)

85. Plaintiff repeats, re-alleges, and incorporates ¶1-84 as set forth in full herein.

86. As shown through the foregoing acts and conduct, Defendants knowingly and intentionally misrepresented Akorn's intent, capacity, and ability to manufacture Fera's Products to Fera prior to the formation of the CMS Agreement, based upon the information disclosed to Akorn concerning Fera's commercial plans and in an effort to acquire Fera's trade secrets in order to manufacture Fera Products for itself.

87. Plaintiff entered into the CMS Agreement in reliance upon Defendants' representations as detailed in ¶18-21, among other paragraphs, that Akorn maintained the capacity (and intent) to manufacture Fera Products in an amount to satisfy Fera's annual forecasts.

88. Plaintiff suffered pecuniary loss amounting to at least \$56,887,493, deprivation of its commercial advantage and loss of market share due to Akorn's intentional delaying of Fera Products from entering the market, together with the loss of Fera's business valuation that is the difference between what a an acquirer would pay for Fera at market price and the actual price paid to acquire Fera in an amount to be determined at trial.

COUNT V:

(For Declaratory Judgment as to Defendant Akorn)

89. Plaintiff repeats, re-alleges, and incorporates ¶1-88 as set forth in full herein.

90. Plaintiff seeks a declaratory judgment holding the following: 1) Fera possess confidential and proprietary information and trade secrets in Fera's marketing and forecasting plans, manufacturing techniques and specifications, drug developments, FDA Process, and the sale and manufacture of Bacitracin; 2) Akorn is required by the terms of the CDA and CMS Agreements to keep all confidential and proprietary information and trade secrets in strict confidence; and 3) Akorn is prohibited from, among other prohibitions, utilizing, in any way, confidential information provided to Akorn by Fera in Fera's manufacturing techniques and specifications, drug developments, FDA Process, and the sale and manufacture of Bacitracin.

COUNT VI:

(For Injunctive Relief as to Defendant Akorn)

91. Plaintiff repeats, re-alleges, and incorporates ¶1-90 as set forth in full herein.

92. The CDA Agreement provides that "Akorn and Fera consents and agrees that either party may seek injunctions, orders or decrees as may be necessary to protect its Confidential Material." Ex. A., Sec. 8.

93. The CMS Agreement provides that "[e]ach Party agrees that the Confidential Information of each Party is vital to the business interests of each Party and that any disclosure or unauthorized use thereof would cause irreparable harm. Each Party may specifically enforce the obligations of the other under this paragraph, by injunction or otherwise..." Ex. B, Sec. 11(e), pg. 13.

94. Given Akorn's wrongful and opportunistic use of Plaintiff's trade secrets in order to obtain the knowledge necessary to duplicate and sell Fera Products for itself, Plaintiff asks this court to grant injunctive relief restraining Akorn from selling Fera's Products in the future.

PRAYER FOR RELIEF

Wherefore, Plaintiff, Fera Pharmaceuticals, LLC, respectfully prays that this Court grant the following:


1. Compensatory damages against Defendants in an amount to be established at trial, but upon information and belief, the amount will exceed \$100,000,000;
2. Punitive damages against Defendants as established at trial;
3. Awarding Plaintiff pre-judgment and post-judgment interest pursuant to CPLR 5001, *et seq.* on all amounts awarded in this action;
4. All reasonable costs incurred herein;
5. Attorneys' fees in an amount to be established at trial; and
6. Such other relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury as to all issues triable of right.

Dated: December 21, 2012
New York, NY

NAPOLI BERN RIPKA SHKOLNIK, LLP

By: 

Paul J. Napoli
Adam J. Gana
350 Fifth Avenue, Suite 7413
New York, New York 10118
(212) 267-3700
Attorneys for Plaintiff

EXHIBIT A

CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

This Confidentiality and Non-Disclosure Agreement ("Agreement"), made this of February 23, 2009 by and between Akorn Inc., with a place of business at 1925 West Field Court, Suite 300, Lake Forest, IL 60045, USA ("Akorn") and Fera Pharmaceuticals, LLC, Locust Valley, NY 11560, USA ("Fera").

WHEREAS Akorn and Fera wish to consider entering into a mutually beneficial relationship for pharmaceutical products ("Purpose");

WHEREAS in the course of considering the above stated relationship it shall be necessary for Akorn and Fera to disclose confidential and proprietary information of each to the other with the expectation that all said disclosed material shall be held in confidence;

NOW THEREFORE, in exchange for mutual promises and other good and valuable consideration, the receipt and sufficiency is hereby acknowledged, the parties agree as follows:

1. "Confidential Material" shall refer to all material, data, knowledge, intellectual property, finances, marketing plans, products, processes, price quotations, business proposals and other information relating to manufacturing capabilities and operations, information, and software of any kind regarding Purpose, whether written or oral, provided to by Akorn and Fera to the other party as a sole and direct result of their relationship, provided however, Confidential Material shall not include:

- a) Information that is now in the public domain or subsequently enters the public domain through no fault of Akorn and Fera.
- b) Information that is in receiving party's possession at the time of disclosure by the disclosing party other than as a result of receiving party's breach of any legal obligation.
- c) Information that is presently known or becomes known to Akorn or Fera from its own independent sources as evidenced by its written records.
- d) Information that Akorn and Fera receive from any third party not under any obligation to Akorn and Fera to keep such information confidential.
- e) Information required to be disclosed by law.

All Confidential Material first disclosed hereunder in a tangible form shall be marked "Confidential." All Confidential Material orally disclosed hereunder shall be confirmed in a writing provided to the receiving party by the disclosing party within 30 days of such first disclosure, but failure to provide such confirmation in writing shall not affect the

nature of the Confidential Material disclosed if such Confidential Material was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

2. Within a reasonable time of execution this Agreement (the date listed first above), each party shall provide and/or disclose to the other, such Confidential Information then in its possession or under its control that it deems to be necessary or useful for the other party to pursue the Purpose.

3. Akorn and Fera each agree to maintain in strict confidence all Confidential Material and to disclose said Confidential Material to their respective employees, agents, consultants and affiliates who have agreed to accept the confidentiality and non-use obligations established by this Agreement on a strict need-to-know basis only. Akorn and Fera each agree to advise any and all such employees, agents, consultants and affiliates of the Confidential Material and each shall ensure that any party to whom Confidential Material is disclosed shall abide by the provisions of this Agreement.

4. All Confidential Material shall be used for the purposes set forth above and for no other purpose without the prior written consent of the entity which originally supplied such Confidential Information to the other party.

5. All Confidential Material shall remain the exclusive property of the entity which originally supplied such Confidential Information to the other party and shall be promptly returned or destroyed upon written request, provided that such other party may retain one complete copy of the Confidential Material for purposes of determining its obligations hereunder.

6. This Agreement, relationship, subject matter, and Purpose shall not be disclosed to any third party without the prior written consent of Akorn and Fera.

7. The failure of Akorn and Fera to enforce any provision of this Agreement shall not operate as a waiver of such provision or of any other provision of this Agreement.

8. Akorn and Fera each hereby agree that any breach of this Agreement may result in irreparable injury and damage that may not be adequately compensable in money damages, and which may have no adequate remedy at law, and therefore each of Akorn and Fera consents and agrees that either party may seek injunctions, orders or decrees as may be necessary to protect its Confidential Material.

9. All Confidential Material is provided "as is" and without any representation or warranty, whether express or implied, as to its accuracy or completeness.

10. No rights or licenses, express or implied, are hereby granted to Akorn and Fera under or in any patents, copyrights, trade secrets, or Confidential Material of Akorn and Fera as a result of, or related to this Agreement.

11. This Agreement shall remain in full force and effect from the execution date for a period of five (5) years, unless extended by mutual agreement of the parties. Upon the expiration or termination of this Agreement, both parties shall either return or destroy any Confidential Information received by them, as requested by the other party.

12.. This Agreement may be executed in separate counterparts, and by facsimile each of which when so executed and delivered shall be an original and all such counterparts shall together constitute one and the same instrument.

13. This Agreement shall be construed in accordance with and controlled by the laws of the State of Illinois, USA.

IN WITNESS THEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives the date first written above.

Akorn Inc.

By: Abu Alam

Name: Dr. Abu Alam

Title: SVP, New Business Development

Date: 3/2/09

Fera Pharmaceuticals, LLC

By: Frank J. Dellaferra

Name: Frank J. Dellaferra

Title: President

Date: 2/24/09

EXHIBIT B

COMMERCIAL MANUFACTURING SUPPLY AGREEMENT

THIS COMMERCIAL MANUFACTURING SUPPLY AGREEMENT (this "Agreement") is effective this (13) day of July, 2009 (the "Effective Date") between Akorn Inc., a Louisiana corporation, having a principal place of business at 1925 West Field Court, Lake Forest, Illinois 60045, United States of America ("Akorn"), and FERA PHARMACEUTICALS, LLC, a New York limited liability company ("Customer"), having a principal place of business at 15R Birch Hill RD, Locust Valley, NY 11560.

("Customer"). Akorn and Customer are sometimes referred to herein individually as a "Party," or collectively, as the "Parties".

RECITALS:

- A. Akorn is in the business of developing, manufacturing and supplying pharmaceutical products.
- B. Customer is in the business of marketing and/or distributing one or more pharmaceutical products.
- C. Customer desires Akorn to manufacture and supply certain FDA-approved pharmaceutical products identified on Exhibit A attached hereto and incorporated herein, which may be amended from time to time in writing by the Parties, and Akorn desires to provide Customer with such services.

NOW, THEREFORE, in consideration of the foregoing and the following mutual promises, the Parties agree as follows:

1. **Definitions.** In addition to other terms that may be defined elsewhere in this Agreement, the following capitalized terms shall have the following meanings:
 - (a) "Affiliate" means with respect to any Party, any party controlling, controlled by or under common control with any such Party. For purposes hereof, "control" and its derivatives means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Party, whether through the ownership of voting securities or voting interests, by contract or otherwise.
 - (b) "Calendar Quarter" means any of the three-month periods beginning January 1, April 1, July 1 or October 1 of a Calendar Year.
 - (c) "Calendar Year" means the time period beginning January 1 and ending December 31 of each year.
 - (d) "Cancellation" means the cancellation of all or any part of a Purchase Order.
 - (e) "Carrier" means the person or entity designated by Customer to transport a Product from Akorn's FOB shipment point to such location indicated by Customer pursuant to a Purchase Order.
 - (f) "cGMP" means applicable current Good Manufacturing Practices as defined by 21 Code of Federal Regulations Section 210, 211 et. seq. or as required by the FDA, or any other Regulatory Authority having the jurisdiction to regulate a Product distributed within the United States.

- (g) "Delivery Date" means the date on which Akorn is to deliver a Product to Carrier as indicated in a Purchase Order.
- (h) "Exclusive" means manufacturing of specified product(s) as identified in Exhibit A solely for Customer over the duration of this agreement
- (i) "Facilities" means any of the manufacturing facilities used by Akorn to manufacture a Product, including, without limitation, those certain facilities located at 150 S. Wyckles Road, Decatur, Illinois 62522, and 1222 W. Grand, Decatur, Illinois 62526 and 72-6 Veronica Avenue, Somerset, NJ
- (j) "FDA" means the United States Food and Drug Administration or any successor agency.
- (k) "FOB shipping point" means the location as designated by Akorn from which Products or other items shall be shipped to Customer pursuant to a Purchase Order or Customer's request, respectively.
- (l) "Insignia" means all trademarks, trade names, logos, symbols, badges, labels, decorative designs, packaging designs or similar trade dress.
- (m) "Intellectual Property Rights" means all United States and worldwide trademarks, service marks, trade dress, logos, copyrights, rights of authorship, inventions, patents, rights of inventorship, moral rights, rights of publicity and/or privacy, trade secrets, rights under unfair competition and/or unfair trade practices laws, and all other intellectual and industrial property rights related thereto.
- (n) "Manufacturing Costs" means Akorn's costs to manufacture a Product, including, but not limited to, the cost of Product Supplies, process development, labor and fully burdened overhead.
- (o) "Products" or "Product" means collectively or individually, respectively, the products listed on Exhibit A.
- (p) "Product Price" means the price to be paid by Customer to Akorn for each bottle/unit of a Product.
- (q) "Product Supplies" means all labeling, package inserts, bottles, tubes, tips, caps, supplies, API, raw materials, and packaging required to make a finished saleable Product, and to ship a finished Product to Customer.
- (r) "Purchase Order" means a written order for a Product submitted by Customer to Akorn (specifying the Quantity Ordered, Delivery Date and the location such Product ordered is to be shipped) subject to the terms and conditions set forth in Section 4 below.
- (s) "Purchase Price" means the total amount due and payable to Akorn for Products shipped pursuant to a Purchase Order, calculated by multiplying the total quantity of a Product actually shipped to Customer (pursuant to the respective Purchase Order) by the applicable Product Price.
- (t) "Semi-exclusive" means manufacturing of specified product(s) identified in Exhibit A solely for Customer and Akorn over the duration of this agreement

- (u) "Quantity Ordered" means the quantity of the Product to be manufactured by Akorn and delivered to Customer as specified in a Purchase Order.
- (v) "Regulatory Authority" means any regulatory agency or any other governmental unit, including, without limitation, the FDA, that has the authority, power and/or the jurisdiction to regulate the use, import, manufacturing, marketing, labeling, sale, and/or the general distribution of a Product.
- (w) "Specifications" means the acceptance criteria upon which the finished Product and any of its Product Supplies (defined above) and bill of materials items are assessed for acceptance or rejection, with regard to pre-established acceptable quality levels and sampling plans. Such meaning of specifications also extends to the formulation, manufacturing instructions, testing and handling requirements, labeling and packaging requirements for a Product as set forth in Exhibit B attached hereto and incorporated herein, as established by Akorn and approved by Customer, which may be amended from time to time to comply with any and all applicable regulations of a Regulatory Authority or changes to cGMP.
- (x) "Term" means the time period in which this Agreement shall be in full force and effect as set forth in Section 12 below.
- (y) "USP" means United States Pharmacopoeia.

2. *Agreement to Manufacture and Purchase. Exclusivity and Semi-Exclusivity.*

- (a) During the Term, Akorn agrees to manufacture and supply Products to Customer on an exclusive or semi-exclusive basis as identified in Exhibit A pursuant to Purchase Orders accepted by Akorn, and Customer agrees to purchase and accept delivery of such Products from Akorn (in no less than the minimum annual quantities set forth on Exhibit D attached hereto and incorporated herein), as its exclusive manufacturer and supplier of the Products and any bioequivalent product, subject to all the terms and conditions set forth in this Agreement.
- (b) Akorn shall manufacture and supply the Products in accordance with the applicable Specifications, cGMP and all other provisions of this Agreement. Additionally, the Parties shall implement a mutually approved Quality Assurance agreement prior to commercial launch of any products defined in Exhibit A.

3. *Price and Payment.*

- (a) Milestone Payments. In consideration of Akorn's support for Commercialization of Products for Exclusive supply under this Agreement and as specified in Exhibit A, Customer shall pay to Akorn the total amount of \$300,000 as a non-refundable, non-recoupable development fee for activities outlined in Exhibit E ("Development Fee"). The Development Fee shall be payable in two installments in the amounts and in accordance with the terms set forth below:
 - (i) Customer shall pay Akorn the amount of \$50,000 upon the Effective Date; and
 - (ii) Customer shall pay Akorn the amount of \$50,000 upon completion of a single exhibit batch for each Exclusive Product (\$250,000 total; 5 products).

- (b) Prices. All payments due and payable to Akorn hereunder shall be made in United States Dollars. Customer shall pay to Akorn the then-effective Purchase Price payable under each Purchase Order based on the then current Product Price for each bottle/unit of a Product, as initially set forth herein.
- (c) Annual Price Adjustments. Akorn shall have the right to modify the Product Prices once per Calendar Year upon thirty (30) days notice to Customer pursuant to Section 16 below; provided however, such increase shall not exceed more than the Producer Price Index (PPI) as defined by the US Department of Labor without Customer's prior written consent. The Parties acknowledge Akorn shall have the additional right to modify a Product Price as set forth in the event Akorn experiences any increase in the Manufacturing Costs. The new Product Price shall be effective upon thirty (30) days notice by Akorn pursuant to Section 16 below.
- (d) Price Adjustments for Material Change. Notwithstanding the terms and provisions of Section 3(c) above, upon any material change(s) to the Manufacturing Costs, the Parties agree to renegotiate the Product Price in good faith (in accordance with the magnitude and effect of the change). Such negotiations shall be completed within sixty (60) days of Customer's receipt of Akorn's written notice thereof describing the nature of the changed circumstances and its initial proposed modifications to a Product Price or terms of this Agreement, as applicable ("Proposed Change Notice"). If the Parties are unable to agree within such sixty (60) day period, (A) either Party may unilaterally terminate this Agreement by providing the other Party a written notice of termination for failure to mutually agree upon a new Product Price or terms of this Agreement, as applicable, which termination shall be effective fifteen (15) days following by the applicable party thereof, or (B) if neither Party terminates this Agreement as set forth in subsection (A) above, such adjusted Product Price and/or modified terms set forth in Akorn's Proposed Change Notice shall (1) be binding on Customer, (2) be deemed automatically incorporated into this Agreement without any further action from either Party (including, without limitation, a written amendment executed by either Party), and (3) the new Product Price and/or modified terms (if any) shall supersede the Product Price or terms (as applicable) previously in effect. For the purpose of this Section any changes that result in an increase in Manufacturing Costs that exceeds fifteen percent (15%) shall be considered a "material change" subject to the provisions of this Section 3(d). Notwithstanding anything to the contrary provided herein, under no circumstances shall Customer be entitled to any discount or decrease to a Purchase Price based on any decrease in Manufacturing Costs.
- (e) Product Payment Period. Akorn shall deliver a written invoice ("Invoice") to Customer with every delivery of a Product pursuant to a particular Purchase Order, indicating (i) the corresponding Purchase Order number (or other equivalent identifier), (ii) the actual shipping date versus the Delivery Date, (iii) the actual quantity of Products shipped versus the Quantity Ordered, and (iv) the Purchase Price for such shipment. If any Purchase Order is fulfilled in multiple shipments, Akorn shall indicate the Delivery Date and quantity such remaining Product will be delivered to Customer in the invoice sent to Customer with the first shipment of such split order. Customer shall pay Akorn the Purchase Price indicated on each Invoice no later than thirty (30) days from the date of Akorn's Invoice.
- (f) Late Payment. Any payment or balance due and payable to Akorn hereunder that remains unpaid ("Late Balance") for more than ten (10) days, shall be subject to a late fee in the amount equal to 0.75% of the Late Balance (to be accrued on a monthly basis). In the event any Late Balance remains past due for more than thirty (30) days beyond the applicable due date, Akorn may, at its sole discretion, (a) terminate this Agreement in accordance with Section 12(d) below, and/or (b) withhold manufacturing, supplying or delivering any Product to Customer from the date Akorn provides Customer written notice

of its intent to exercise its right set forth in this subsection (b) until the date on which Customer satisfies and pays such Late Balance, including, any amounts accrued as late fees as provided herein.

4. **Purchase Orders.**

- (a) Terms and Conditions of Purchase Orders. Upon execution of this Agreement, Customer shall submit to Akorn Customer's standard purchase order form for Akorn's review and written approval. Upon Akorn's approval, all Purchase Orders delivered to Akorn by Customer under this Agreement shall be delivered to Akorn in writing on such form and such form shall not be substituted or modified without Akorn's prior written consent. Notwithstanding anything to the contrary set forth in Section 4(b) below, any Purchase Order delivered to Customer in a form other than the form approved by Akorn shall be deemed rejected by Akorn and shall be void unless (i) Akorn delivers Products pursuant to and accordance with such Purchase Order, or (ii) Akorn delivers written notice to Customer it intends to fulfill such Purchase Order, whichever event occurs first. Each Purchase Order shall specify the Quantity Ordered, Delivery Date, Carrier, and any special shipping or handling instructions that may be requested by Customer. Purchase Orders shall be delivered to Akorn not less than ninety (90) days prior to the Delivery Date requested. In the event a Purchase Order is received by Akorn within less than ninety (90) days of the applicable Delivery Date, the Delivery Date of such Purchase Order shall be automatically revised (without notice to Customer) to such date that is ninety (90) days following the actual date on which the particular Purchase Order is received by Akorn. Notwithstanding the preceding sentence, Products under Customer's first Purchase Order shall be delivered by Akorn as soon as practicable after Akorn notifies Customer in writing it has proceeded to commercial batch production following the completion (and approval of Customer) of Akorn's engineering batches. Customer acknowledges and accepts Akorn's approval and use of Customer's standard purchase order form as provided in this Section is intended as an accommodation to Customer only. Accordingly, any preprinted terms contained in any Purchase Order that is intended to modify, be incorporated into, be in addition to, or are in consistent with any of the terms of this Agreement shall be null and void and have no force or effect unless otherwise expressly agreed upon by Akorn in writing. The foregoing provision shall apply whether any such preprinted terms were included in Customer's standard purchase order form at the time such form was submitted to Akorn for approval as set forth above.
- (b) Forecasts. On the Effective Date, and continuing each Calendar Quarter during the Term, Customer will provide Akorn with a twelve (12) month rolling forecast ("Forecast") projecting the estimated quantity of a Product Customer will purchase for each month in a Calendar Year. Each Forecast shall begin with first day of the next upcoming Calendar Quarter and be delivered to Akorn in writing at least thirty (30) days before the end of the current Calendar Quarter. Akorn shall have the right to reject a Forecast or refuse to manufacture and supply any quantity of Products in the event that such Forecast exceeds the plants available capacity. Should Akorn reject a Forecast, or any portion thereof, the Parties shall negotiate in good faith to revise the Forecast to be mutually acceptable to both Parties. For avoidance of doubt Customer shall have product priority with respect to production of the Products identified in this agreement should Akorn enter the market with generic versions of such Products. In the event that Customer's orders in any quarter are more than ten percent (10%) less than the quantity provided in the Forecast for the same quarter, then Customer shall pay to Akorn a sum equal to the difference between the Forecast and the price for the actual Purchase Price for the quantity ordered.
- (c) Cancellation of Purchase Orders. Customer acknowledges Akorn's manufacturing schedule of a Product is based on the Delivery Date indicated by Customer in each

Purchase Order. As such, cancellation of a Purchase Order (or any part thereof) by Customer within two (2) weeks of the date on which Akorn must commence manufacturing a Product to meet the applicable Delivery Date as set forth therein ("Manufacturing Date") will result in a "Cancellation Fee" in the amount equal to the cost of any and all in-process components incurred and labor expended by Akorn to reasonably necessary to fulfill the Purchase Order prior to Customer providing notice to Akorn of such cancellation, not to exceed twenty five percent (25%) of the applicable Purchase Price (or the pro rata part thereof, as the case may be). All cancellation fees due and payable to Akorn pursuant to this Section shall be paid by Customer within thirty (30) days of Customer's receipt of a written invoice from Akorn setting forth the applicable Cancellation Fee.

5. **Raw Materials and Other Supplies.**

- (a) **Product Supplies and Property Rights.** Akorn shall use commercially reasonable efforts to perform all the activities to commercialization as set forth on Exhibit C, and supply all Product Supplies and capital equipment necessary to manufacture Products in accordance with the Specifications and the terms of this Agreement. Customer acknowledges that the Specifications and the activities identified on Exhibit C, include or incorporate certain data, technical know-how, formulations, and Intellectual Property Rights related thereto (collectively, "Technical Know-How") owned by Akorn. Each of the Parties acknowledge and accept that except for any new Product-Specific Technical Know-How (as defined below), each of the Parties' Technical Know-How existing as of the Effective Date, and all derivatives, enhancements, and improvements thereof shall remain the sole property of such respective Party. Accordingly, any Technical Know-How specifically developed solely with respect to the manufacture of a Product and having no other general application with any other product or process that created or developed in joint cooperation and efforts of the Parties ("Product-Specific Technical Know-How") shall be deemed the joint property of both Parties, with each Party having the equal and non-exclusive right to use, and permit the use thereof, to any third party in connection with the development of any other product or such other use it deems appropriate. The Parties agree not to challenge, contest or otherwise impair (or attempt to impair) the ownership and rights relating to any matters described in this Section, or the validity or enforceability of any Intellectual Property Rights related thereto.
- (b) **Raw Material Testing.** Akorn shall perform testing to each lot of an Active Pharmaceutical Ingredient (hereinafter "API") received from a third-party vendor to be used in the manufacturing of a Product in accordance with cGMP (or as may be required by a Regulatory Authority having jurisdiction thereof).
- (c) **API and Product Handling.** Akorn shall store the API and all Product Supplies in accordance with the Specifications and cGMP.
- (d) **Shipping.** All Product shall be delivered Akorn's FOB shipping point to the Carrier. Akorn shall use commercially reasonable efforts to deliver Product by the applicable Delivery Date indicated in a Purchase Order, but failure to do so shall not be deemed a breach of this Agreement. Product shall be shipped to a single location within the continental United States to the designated location indicated in each Purchase Order. Prior to releasing any shipment pursuant to a Purchase Order, Akorn shall deliver a packing slip to Customer (via, at Akorn's discretion, regular mail, facsimile or electronic mail) indicating (i) the Purchase Order number (or other equivalent identifier), (ii) the number of units/bottles of a Product included in such shipment, (iii) the actual date on which such Purchase Order is expected to leave Akorn's FOB shipping point, and (iv) the date on which such shipment is anticipated to be delivered to its destination indicated in the Purchase Order (if different than the Delivery Date). Customer is responsible for all costs and expenses associated

with the shipment of a Product pursuant to a Purchase Order, including, all costs for packing materials, labor, cartage, and such charges incurred to follow any special delivery instructions from Customer included in particular Purchase Order.

- (e) Risk of Loss. Title to a Product shipped pursuant to a Purchase Order shall transfer from Akorn to Customer upon delivery from Akorn to Carrier Akorn's shipping point, and Customer shall solely bear the risk of loss by reason of theft, casualty, or other cause of any Products thereafter.

6. *Quality Assurance and Documentation by Akorn.*

- (a) Process. Akorn shall conduct all quality control and process testing applicable to a Product in accordance with Akorn's standard operating procedures, cGMP, and all applicable regulations or requirements of a Regulatory Authority (if any).
- (b) Documentation. Akorn shall provide Customer with a copy of the batch documentation for each lot of a Product reflecting such batch complies with all quality control criteria identified in Subsection 6(a) above. Upon written request from Customer, Akorn shall provide to Customer summaries of other lot specific documents or data (for lots manufactured for the Customer) created or maintained by Akorn in the ordinary course of manufacturing a Product within seven (7) calendar days of receipt thereof.

7. *Quality Assurance, Sampling and Inspections By Customer.*

- (a) Inspection Visits. Not more than once per Calendar Year (unless otherwise mutually agreed to in writing by Akorn and Customer), Customer shall have the right, at a mutually agreeable time and upon mutually agreeable terms, during Akorn's regular business hours, to enter any Facilities for the purpose of observing the manufacturing of a Product, inspecting the quality of a finished Product, obtaining samples of a Product and/or conducting quality assurance audits of aspects directly related to a Product (collectively, "Inspection Purposes").
- (b) Production Visits. Notwithstanding anything to the contrary provided above, Customer shall have the right to visit and enter into any Facilities upon prior written consent from Akorn, which consent may not be unreasonably withheld, to observe the manufacturing process of specific lots of Product intended for the Customer, provide responses or guidance as may be requested from Akorn (or Facilities representative), and/or conduct such other activities relating to the production or manufacturing support of a Product, other than those relating to any Inspection Purposes; provided, however, such visitation right as provided in this Section (i) shall be limited to the particular Facilities and periods in which a Product for Customer is actually being manufactured pursuant to this Agreement, and (ii) is subject to the same requirements and indemnity set forth in Section 7(c) below. Akorn shall have the right to cancel Customer's right to visit any Facilities as provided in this Section with written notice to Customer at anytime if, Akorn determines in its sole and absolute discretion, Customer's presence in any of the Facilities hinders, interferes with or is deemed problematic.
- (c) Visit Requirements. Any person designated or authorized by Customer to enter into any Facilities in connection with Customer's rights as set forth in Sections 7(a) or 7(b) above, such person shall (i) comply with any internal rules and requirements of Akorn, and (ii) execute and deliver to Akorn (if provided and requested by Akorn) such documentation or instrument certifying that such person understands the dangers of entering into the Facilities and that he or she enters such Facilities at its own risk of harm, loss, and/or damage to person and property, and agrees to hold Akorn harmless for any such harm,

loss, and/or damage to person and property. Any person entering into any Facilities on behalf of Customer as provided herein shall be an employee or independent contractor under an valid/active contract with Customer that is covered under Customer's general liability insurance (or such other type of insurance policy as appropriate). Customer agrees to (i) assume all risk of loss or claim that may be brought against Akorn, the respective Facilities, and any Affiliates of Akorn or the Facilities, including, without limitation, all officers, directors, employees, and/or agents of such parties (collectively, "Indemnitees"), (ii) indemnify, defend and hold all Indemnitees (collectively and individually) harmless of any claims arising out of a visit to the Facilities as provided herein, and (iii) hereby releases one or all of the Indemnitees, as may be applicable, against any and all liability resulting from Customer or any Inspector visiting the Facilities in connection with Customer's inspection rights provided hereunder.

- (d) Notification of Inspection. Each of the Parties agree to notify the other Party in writing within five (5) working days of being notified of any of the following: (i) any inspections of the Facilities by the FDA, or other Regulatory Authority, for purposes specific to a Product, (ii) any pending or threatened litigation, governmental investigation, proceeding or action involving or pertaining to a Product, or (iii) any defective, adulterated or misbranded Product which has been distributed.
- (e) Annual Report. Annually, Akorn shall generate a summary report identifying any and all incidents of an adverse drug reaction to a Product that Akorn was directly notified of or becomes aware of during the year. Customer acknowledges and accepts any and all information provided in such report shall be to the best of Akorn's knowledge without the obligation of investigation or inquiry, or duty or implied duty to investigate or make any inquiries thereof, and shall be limited to information and facts as made know to Akorn. Customer shall rely on any information provided in such report at its own risk and the indemnity provisions set forth in Section 9(a) shall not apply to any claim arising from or related to any way whatsoever to Customer's use, dissemination or reliance thereof.
- (f) Product Complaints. Upon written request from either Party, the Parties agree to cooperate with each other to investigate any complaints concerning a Product, including, without limitation, any complaint concerning an adverse drug event. If deemed necessary by Akorn, or upon the request of Customer, Akorn shall use commercially reasonable efforts to analyze the applicable Product and produce a written report of its analysis. Customer shall bear all costs and expense for any testing performed by Akorn at the request of Customer, including, any testing that is outside Akorn's usual course of investigation under its applicable standard operating procedures (SOPs) for complaints, or not otherwise required by regulation. In the event either Party determines that any additional physical, chemical, biological, or other evaluation is necessary to fully investigate a complaint concerning a Product, the Party making such determination shall so advise the other Party in writing and Akorn shall conduct the necessary evaluations, at Customer's sole cost and expense, and shall produce a written report (a copy of which shall be promptly delivered to Customer) of the results.
- (g) Recall Action. If either Party becomes aware of or initiates a recall, withdrawal or field correction of a Product hereunder (collectively, "Recall Action"), the Parties shall immediately notify the other of such Recall Action, and agrees to coordinate and cooperate with each other Party in any manner reasonably necessary to timely comply with all necessary actions, and applicable laws and regulations relating to such Recall Action subject to the terms set forth in Section 7(h) below.
- (h) Recall Action initiated by Customer. In the event that Customer should voluntarily decide to initiate a Recall Action of a Product supplied to Customer by Akorn under this Agreement,

Customer shall notify Akorn's Executive Vice President of Global Quality Assurance and Legal Department in writing setting forth the reason for such Recall Action, together with an outline of Customer's proposed action plan and a copy of all proposed correspondence, bulletins or other communication that will be distributed in connection with such action plan. Under no circumstances shall Customer commence any activities relating to a Customer initiated Recall Action without first notifying Akorn in writing as provided in this Section. All activities relating to a Recall Action initiated by Customer shall be handled by Customer, unless otherwise notified in Akorn in writing that Akorn will handle such coordination, and the Parties shall fully cooperate with the other Party to the extent reasonably necessary to assist in the investigation and related due diligence to determine the cause and the extent of the issue or matter necessitating such Recall Action.

- (i) Expenses. Customer shall bear all of the costs and expenses of any Recall Action (regardless whether such action is initiated by Akorn, Customer or a Regulatory Authority) including, without limitation, expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and the costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those customers (collectively, "Recall Costs"); provided, however, if such Recall Action is shown to be solely a result of (1) the failure of Akorn to supply Product that conforms to Akorn's warranty set forth in Section 8; (2) Akorn's failure to comply with cGMP in the event of any FDA initiated Recall Action; or (3) the gross negligence or intentional wrongful act of Akorn, Akorn shall bear all of costs and expenses of such Recall Action, including, without limitation, all Recall Costs.
- (j) Recall Records. Each of the Parties shall maintain complete and accurate records relating to the shipment, transportation, distribution and sale of a Product under this Agreement in accordance with all applicable law and regulations of any Regulatory Authority having jurisdiction thereof, but in no event shall such records be maintained for a period less than (i) three (3) years, or (ii) the period consistent with their respective internal record-keeping procedures, whichever period is longer.
- (k) Safety Procedures. Akorn and Customer shall mutually develop safety procedures for the handling and manufacture of a Product and treatment or disposal of wastes relating thereto that comply with all federal and state environmental and occupational safety and health requirements. Such procedures shall be included in a separate document and shall be followed by Akorn in performing services under this Agreement. Upon written request of Customer, Akorn shall ship any Product Supplies that are rejected for non-conformance to applicable Specifications or are defective to such destination at Customer's sole cost to a single destination Customer may designate. The expense for disposal or reclamation of a rejected Product, or Product Supplies, and other waste created from the manufacture of a Product shall be borne by Customer; provided, however, the expense for disposal of rejected Product due to failure of Akorn to perform any of its obligations under this Agreement shall be borne by Akorn.
- (l) Distribution Responsibilities.
 - (i) Customer is responsible for: (1) the resale, handling and distribution of Products in accordance with applicable Specifications, and all requirements of the applicable Regulatory Authority (if any); (2) keeping Akorn updated with the name and contact of such person(s) (with the authority to make decisions on behalf of Customer) that should be contacted to address any matters that may arise during the manufacturing or transit of a Product.

- (ii) Akorn is responsible for: (1) stability testing program; (2) maintaining retention samples, if any; (3) manufacturing, labeling and packaging of a Product in accordance with applicable Specifications, and all requirements of the applicable Regulatory Authority (if any).
- (m) Product Inspection. Akorn will test and inspect each lot of a Product for compliance with the applicable Specifications prior to releasing or delivering a Product pursuant to a Purchase Order to Carrier.
 - (i) Undisputed Rejection. If such noncompliance is undisputed, Akorn shall replace the affected or non-complying Product at Akorn's sole cost and expense (including, the cost of labor and Product Supplies to manufacture the replacement quantity, and all shipping costs to deliver such replacement quantity) as soon as practicable following its receipt of Customer's noncompliance notice. Any Product replaced by Akorn as provided hereunder for noncompliance to Specifications or otherwise shall be, at Akorn's election and expense, either (1) returned to Akorn; or (2) be destroyed by Customer (in such manner specified by Akorn). Akorn shall deliver to Customer instructions indicating whether it has elected the actions described in clause (1) or (2) above in writing within a reasonable amount of time following its receipt of Customer's noncompliance notice as provided herein.
 - (ii) Disputed Rejection. If Akorn disputes Customer's conclusion that a Product lot does not comply with its applicable Specifications, and such dispute is not resolved between the Parties within sixty (60) days of Customer's written notice thereof, such dispute shall be resolved by (1) an action plan approved and acceptable to each of the Parties, or (2) an independent testing organization or consultant registered with the FDA (or other Regulatory Authority having jurisdiction over such matters) and approved by the Parties, which approval may not be unreasonably withheld or delayed by either Party. The determination of such testing entity with respect to all or part of any shipment of a Product shall be final and binding upon the Parties, but only as to the matters identified by Customer in its rejecting of the subject shipment (or portion thereof), and such decision shall have absolutely no effect on any other matters, regardless if the opinion or information provided by such entity includes facts or analysis on matters outside the scope of the nonconformity or noncompliance issues identified by Customer. The fees and expenses of the third party making the determination shall be paid by the Party against which the determination is made.

8. **Warranty.**

- (a) Akorn Warranty. Akorn warrants that each Products, at the time such Product is delivered to Carrier, will meet its applicable Specifications; provided, however, any failure to meet the Specifications resulting from (i) any modifications required and made by Akorn to comply with cGMP or any requirements of the applicable Regulatory Authority, or made pursuant to any instructions from Customer, or (ii) if the Product is abused, mishandled, altered, improperly stored, or repackaged after Akorn delivers a Product to Carrier, shall not constitute a breach of Akorn's obligations of warranty hereunder. No warranty is made as to the quality or suitability of any Product Supplies or any performance characteristics of the Product.
- (b) Warranty Procedures. To claim any rights or to enforce any warranty provisions against Akorn, written notice of a warranty claim must be given by Customer to Akorn within thirty (30) days after the applicable Delivery Date of the subject Product. Any Product that

Customer believes breaches the warranty set forth in Section 8(a) above must be held by Customer for Akorn's inspection and testing and, upon Akorn's written request, returned to Akorn's original FOB shipping point, freight prepaid. Upon Akorn's reasonable determination that the subject Product does not comply with its applicable Specifications when it was delivered to Carrier, Akorn shall, at its election, replace such defective Product with Product conforming to Specifications, or credit Customer for the Purchase Price for the quantity of a Product determined defective by Akorn. If any finding of Akorn that the Product complies or complied with its applicable Specifications when such Product was delivered to Carrier, the subject Product shall be submitted to an independent third party (approved by both Parties) for further testing as provided in Section. If such third party determines that the Product does not comply with its applicable Specifications, Akorn shall, at its election, replace such defective Product with Product conforming to Specifications, or credit Customer for the Purchase Price for the quantity of a Product determined defective by Akorn. If such third party determines that the Product complies with its applicable Specifications, then Customer shall pay the expenses associated with such third party testing and shall accept the subject Product and deliver payment therefor to Akorn within thirty (30) days following the date of receipt of such third party's determination. All decisions of any third party's testing as provided herein shall be final and binding on the Parties.

- (c) Exclusive Remedy. Customer acknowledges and accepts the provisions set forth in this Section 8 shall be Customer's sole and exclusive remedy against Akorn for breach of warranty, breach of contract, tortious acts or any other legal theory arising out of or related to this Agreement, and waives all other rights or other remedies that may be available under law or equity against Akorn for breach of any covenants of Akorn provided hereunder with respect to a Product. Any litigation or cause of action arising out of or relating to this Agreement must be commenced or filed in a court of appropriate jurisdiction and served upon Akorn within two (2) years after the act or failure to act that gives rise to such litigation or cause of action has occurred. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, IN NO EVENT SHALL AKORN BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES, WHETHER FORESEEABLE OR NOT, THAT ARE IN ANY WAY RELATED TO THIS AGREEMENT.
- (d) OTHER WARRANTIES. EXCEPT AS SET FORTH IN THIS SECTION 8, AKORN EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES REGARDING THE PRODUCTS, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS OR BASED ON COURSE OF CONDUCT OR TRADE CUSTOM OR USAGE.

9. ***Indemnification for Third Party Claims.***

- (a) Akorn Indemnification. Akorn shall indemnify and hold Customer harmless from any damage, expense, loss or liability, including, without limitation, reasonable attorney's fees, in connection with any third party claim directly arising out of, resulting from or based upon (i) any defect of a Product which would be a defect covered under Section 8(a) and not a result of the exclusions set forth therein; or (ii) the negligence or willful misconduct of Akorn; provided, however, that Akorn shall not have any obligation to indemnify Customer to the extent that the claim relates to or results from (i) the negligence or willful misconduct of Customer or Carrier, (ii) a breach of any of Customer's obligations under this Agreement, or (iii) any act or failure to act as may be required of Customer hereunder in compliance with any of Akorn's obligations under this Agreement. Notwithstanding anything to the contrary herein, the indemnification set forth in this Section 9 shall not expand the scope of the express warranty set forth in Section 8. Customer shall deliver

written notice to Akorn of any claim for which Customer may be entitled to seek indemnification from Akorn as set forth above as soon as practicable following first becoming aware of any such claim, and agrees to fully cooperate with Akorn in the defense of such claim, including, without limitation, delivering or providing (as applicable) any and all data, correspondence and records that may be requested by Akorn in a timely manner. Notwithstanding the foregoing, at their election, and at their own expense, Akorn and/or its insurers may assume direction and control of the defense of any such claim.

- (b) Customer Indemnification. Customer shall indemnify and hold Akorn harmless from any damage, expense, loss or liability, including, without limitation, reasonable attorney's fees, in connection with any third party claim directly arising out of, resulting from or based upon (i) Customer's operation of its business, including, but not limited to, any failure of Customer to comply with any law or regulation regarding the possession, distribution, sale of the Product, (ii) the negligence or willful misconduct of Customer or Carrier, (iii) a defect or nonconformity of the Product which would not be a defect covered under Section 8.; or (iv) any claim that Customer Insignia or any other Customer materials violates or infringes any third party Intellectual Property Rights. Akorn shall deliver written notice to Customer of any claim for which Akorn may be entitled to seek indemnification from Customer as set forth above as soon as practicable following first becoming aware of any such claim, and agrees to fully cooperate with Customer in the defense of such claim, including, without limitation, delivering or providing (as applicable) any and all data, correspondence and records that may be requested by Customer in a timely manner. Notwithstanding the foregoing, at their election, and at their own expense, Akorn and/or its insurers may assume direction and control of the defense of any such claim.

10. Insurance.


- (a) Akorn's Insurance. Akorn shall maintain (or if applicable, require such third party to maintain) (i) products liability insurance with a minimum limit of \$5,000,000; (ii) comprehensive general liability insurance with minimum limits of \$1,000,000 for each of bodily injury and property damage; and (iii) fire and casualty insurance on the Facilities and their contents. Such policies of insurance shall provide that Customer will be notified at least thirty (30) days prior to any cancellation. Certificates evidencing such insurance shall be provided to Customer upon receipt of written request.
- (b) Customer's Insurance. Customer shall maintain (i) products liability insurance with a minimum limit of \$5,000,000; and (ii) comprehensive general liability insurance with minimum limits of \$1,000,000 for each of bodily injury and property damage. Such policies of insurance shall provide that Akorn will be notified at least thirty (30) days prior to any cancellation. Certificates evidencing such insurance shall be provided to Akorn upon request.

11. Confidential Information.

- (a) "Confidential Information" for purposes of this Agreement means any and all information, trade secrets and know-how of or data about each of the Parties, their clients, or their operations and other matters of a confidential or proprietary nature, including, without limitation, a Product and its Specifications, but shall not include any of the following information:
 - (i) information which was known to the receiving Party, prior to receipt from the delivering Party, as evidenced by the receiving Party's written records;

- (ii) information which can be shown to have been in the public domain or generally known to the trade at the time of receipt from the delivering Party;
 - (iii) information which, other than by breach of this Agreement, can be shown to have entered the public domain or becomes generally known to the applicable trade in which the Parties participate;
 - (iv) information which is disclosed to the receiving Party by a third party unrelated to either Party who is free to make such disclosure;
 - (v) information which that can be shown to have been independently developed by the receiving Party without use of any Confidential Information of the delivering Party; or
 - (vi) information which is required to be disclosed by law, regulatory, administrative or judicial order.
- (b) Prohibited Use. During the Term, including any extension thereof, and for a period of five (5) years thereafter, the Parties shall not disclose, communicate or otherwise make available to any third party, and shall not use or deal with in any manner (except as permitted by this Agreement) any Confidential Information of the other Party, nor shall a Party utilize Intellectual Property Rights disclosed in any patent of either Party, other than as required to manufacture or supply a Product or any other purpose as may be required for the Parties to perform its respective obligations under this Agreement; provided, however, for any Confidential Information that constitutes a trade secret of a Party shall continue for as long as the same remains a trade secret of that Party notwithstanding any limitation or exceptions provided herein.
- (c) Permitted Use. Each Party (i) agrees to use the Confidential Information of the other Party only for the purpose of performing its obligations under this Agreement; (ii) shall not copy any Confidential Information of the other except as necessary to perform its obligations under this Agreement; (iii) shall limit dissemination of the Confidential Information of the other Party to only those persons or other third parties of who have a need to know in order to consummate the intent of this Agreement; and (iv) shall return all Confidential Information (delivered in physical or electronic form) of the other Party, including, without limitation, any copies, upon the earlier of such Party's request or the termination of this Agreement; provided, however, a Party may retain a copy of any Confidential Information of the other Party for record keeping purposes if required by law or regulation.
- (d) Permitted Disclosure. A Party may disclose Confidential Information of the other Party to a third person if it is required to do so by subpoena, court order, law or regulation. In such event, the Party shall, in advance of the disclosure if practical, notify the other of such required disclosure.
- (e) Enforcement Rights. Each Party agrees that the Confidential Information of each Party is vital to the business interests of each Party and that any disclosure or unauthorized use thereof would cause irreparable harm. Each Party may specifically enforce the obligations of the other under this paragraph, by injunction or otherwise, in addition to and not in limitation of any other remedies that a Party may have at law or in equity

12. Term and Termination.

- (a) Term. This Agreement shall commence on the Effective Date and shall continue for a period of seven (7) years, unless earlier terminated as provided hereunder. All references to the Term in this Agreement shall also include any renewal term(s) pursuant to Section 12(c) below.
- (b) Discretionary Termination. Akorn shall have the right, in its sole discretion, to immediately terminate this Agreement upon a ten (10) day written notice to Customer should (i) any Customer Insignia infringe or be likely to infringe any third party Intellectual Property Rights or (ii) Customer fail to fulfill the minimum annual quantity purchases for any one calendar year period as set forth in Exhibit D. Seven (7) 
- (c) Renewal Term. The Parties may renew this Agreement for successive five (5) year terms upon their mutual written agreement prior to the lapse of the initial ~~five (5)~~ year term, and thereafter, prior to the lapse of the then-current five (5) year renewal term, by giving the other Party a six (6) month prior written notice in each such case.
- (d) Mutual Right to Terminate. Either Party may terminate this Agreement for a material breach by the other Party by giving the breaching Party written notice, specifying the breach relied on, and giving the breaching Party thirty (30) days to cure such breach, except any breach by Customer to make a payment when due hereunder must be cured within ten (10) days from receipt of Akorn's written notice thereof. If the breach has not been cured (or the breaching Party has not commenced a good faith effort to cure) at the end of the thirty (30) day period, then, upon notice thereof to the breaching Party by the other, this Agreement shall immediately terminate.
- (e) Effect of Termination. The termination of this Agreement shall not relieve the Parties of any obligation accruing prior to termination, provided that unless otherwise mutually agreed by the Parties in writing, a Purchase Order outstanding as of the effective date of an early termination shall remain in effect only to the extent of work in progress as of the date of notice of termination. Without limitation as to other rights and obligations that may survive, Section 1, 8(c), 8(d), 9, 10, 11, 12(e), 14, 16, 20 and 22 shall survive any termination of this Agreement.
13. **Independent Contractor**. Notwithstanding anything to the contrary provided herein, Akorn is an independent contractor for Customer, and the Parties are not partners or joint ventures, and Akorn shall have the right to establish and follow its own internal procedures to comply with its obligations hereunder. Except for any special shipping or handling instructions provided by Customer in a particular Purchase Order, all decisions pertaining to labor, components necessary for the manufacture and the supply of a Product, maintenance of required governmental permits and compliance with all laws regarding the Facilities or the manufacture of a Product shall be the sole responsibility of Akorn and not subject to any direction or rights of Customer.
14. **Dispute Resolution**.
- (a) (i.) Good Faith Negotiation. The Parties agree that, before resorting to any formal dispute resolution process concerning any dispute arising from or in any way relating to this Agreement (a "Dispute"), they will first attempt to engage in good faith negotiations in an effort to find a solution that serves their respective and mutual interests, including their continuing business/professional relationship. Party-principals agree to participate directly in the negotiations. Unless otherwise agreed in writing, the Parties shall have five (5) business days from the date the questioning party gives Notice (defined below) of the particular issue to begin these negotiations and 15 business days from the Notice date to complete these negotiations concerning the Dispute.

(ii) Mediation. If the negotiations do not take place within the time provided in "i" above, or if the negotiations do not conclude with a mutually agreed upon solution within that time frame (or its agreed upon extension), the Parties agree to mediate any Dispute. If the Parties cannot agree upon a mediator, each shall select one name from a list of mediators maintained by any bona fide dispute resolution provider or other private mediator; the two selected shall then choose a third person who will serve as mediator. The Parties agree to have the principals participate in the mediation process, including being present throughout the mediation session(s). The Parties shall have 45 calendar days within which to commence the first mediation session following the conclusion of their good faith negotiations or expiration of the time within which to negotiate (as stated in "i" above). The Parties agree that any mediated settlement agreement may be converted to an arbitration award or judgment (or both) and enforced according to the governing rules of civil procedure. The Parties further confirm their motivating purpose in selecting mediation is to find a solution that serves their respective and mutual interests, including their continuing business/professional relationship.

(iii) Arbitration. If the mediation provided for in "ii" above does not conclude with an agreement between the Parties resolving the Dispute, the Parties agree to submit the Dispute to binding arbitration. If the Parties cannot agree on an arbitrator, the person who served as mediator shall select the person to serve as arbitrator from a list compiled by the Parties or, where the Parties do not compile a list, from a list maintained by a bona fide dispute resolution service provider or private arbitrator. The arbitrator's award prepared by the arbitrator shall be final, binding and may be converted to a judgment by a court of competent jurisdiction upon application by either party. The arbitrator's award shall be a written, reasoned opinion (unless the reasoned opinion is waived by the parties). The Parties shall have ten (10) business days from the termination of the mediation to appoint the Arbitrator and shall complete the arbitration hearing within six (6) months from the termination of the mediation. The arbitrator shall have the authority to control and limit discovery sought by either party. The arbitrator shall have the same authority as a court of competent jurisdiction to grant equitable relief, and to issue interim measures of protection, including granting an injunction, upon the written request with notice to the other party and after opposition and opportunity to be heard. The arbitrator shall take into consideration the Parties' intent to limit the cost of and the time it takes to complete dispute resolution processes by agreeing to arbitrate any Dispute.

(iv) Costs. The Parties agree to share the mediator's and arbitrator's fees equally. If the Dispute is arbitrated, the arbitrator may include in any award the right to recover mediator and arbitrator fees, along with any other recoverable costs.

(v) Attorney's Fees. The prevailing party in any arbitration may, in the arbitrator's discretion, be entitled to an award of attorney's fees incurred in arbitrating the Dispute.

(vi) Notice of Dispute: The Notice required under this section shall be in writing. It shall provide sufficient details of the Dispute to apprise the other party of the basis of the disputant's claims. The Notice should include the invitation to begin negotiation, and where unsuccessful, mediation. The date of delivery of the Notice shall be the triggering date upon which the time deadlines in this section will be calculated.

- (b) Governing Law. In arriving at their decision, the arbitrators shall consider the pertinent facts and circumstances and shall be governed by the terms and conditions of this Agreement. To the extent necessary for resolution of a dispute, the arbitrators shall apply the substantive laws of the State of Illinois. To the extent that the Rules and the provisions hereof do not provide for any matter relating to or arising out of the conduct of the

arbitration proceedings, the matter in question shall be determined in accordance with the procedural law of the State of Illinois.

- (c) Specific Performance. The arbitrators are not authorized to award special, indirect, consequential or punitive damages. The arbitrators are authorized to award interest. The arbitrators are also authorized to award interim and specific performance. N.Y. 40
 - (d) Effect of Decision. The decision of the arbitrators shall be an award under Illinois law. The award shall be final and binding on the Parties and judgment upon the award may be entered in and enforced by any court having jurisdiction thereof. Neither Party shall seek recourse to the courts of any country to appeal said award.
 - (e) Expenses. The reasonable expenses of the arbitration, including the arbitrators fees, shall be shared as the arbitrators may determine. The expenses incurred in enforcing the award shall be paid by the Party resisting the enforcement of the award.
 - (f) Permitted Disclosures. The arbitrators shall issue a written decision providing the reasons for their decision. Neither a party, witness nor the arbitrators may disclose the contents or results of any arbitration hereunder without the prior written consent of both the Parties, unless and then only to the extent required by law or as normal and necessary for financial and tax reports and audits.
15. **Labeling.** Product labeling (primary, secondary, insert) and government filings (if any) shall bear the Insignia as provided by customer and approved by Akorn and/or the applicable Regulatory Authority and may indicate that Akorn has manufactured the Product for Customer. Except as specifically contemplated in this Agreement or otherwise required by applicable law and regulations, or to seek approval from any applicable Regulatory Authority, neither Party shall make any other use of the other Party's name or Insignia without the other Party's express prior written approval. To the extent that the labeling contains the Customer's Insignia, Customer hereby represents and warrants that it holds all rights to its Insignia and that the use by Akorn in manufacturing Product and distribution and sale by Customer and its representatives shall not infringe or violate the Intellectual Property Rights of any third person.
16. **Attorney's Fees.** A defaulting Party shall pay all expenses, reasonable attorneys' fees and court costs incurred in good faith by the other Party in enforcing the terms of this Agreement, if such other Party obtains a settlement, judgment or ruling in its favor on the substantive issue presented.
17. **Notices.** All notices to be given under this Agreement shall be in writing and shall be delivered personally, by facsimile machine with a copy mailed by certified mail, or by certified mail postage prepaid, to the following addresses:

If to Akorn: Akorn, Inc.
Attn: Contract Manufacturing
1925 West Field Court
Lake Forest, IL 60045

Copy: Legal Department

If to Customer: FERA PHARMACEUTICALS
15R Birch Hill Rd
Locust Valley, NY 11560
Attn: Janet L. DellaFera

Notices shall be effective upon receipt if personally delivered; on the first business day following the date of facsimile transmission; or on the third business day following the date of mailing. A Party may change the address for notices by notifying the other Party of such change in accordance with this Section.

18. **Assignment and Subcontracting.** This Agreement shall not be assigned by a Party without the prior written consent of the other Party, provided, however, that no consent shall be required in the event that Akorn assigns this Agreement (and/or any of its obligations hereunder) to an Affiliate of Akorn or should Akorn merge with or sell all or substantially all of its assets to a third party which shall agree to perform in accordance with the terms and conditions of this Agreement. Except for any obligation provided hereunder relating to the manufacturing of Product, Akorn may use subcontractors and other independent third parties in the performance of its other obligations under this Agreement without written approval of the Customer. In the event, Akorn desires to assign any of its manufacturing obligations hereunder, Akorn shall request Customer's consent (which consent shall not be unreasonably withheld) to such assignment in writing indicating the proposed manufacturer, the location of its facilities, and evidence such facilities comply with all applicable requirements of the FDA or other Regulatory Authority having jurisdiction thereof. For the purposes of this Section, Customer withholding its consent of any facility or manufacturer that meets all applicable inspection requirements under cGMP and/or is approved by the FDA shall be considered unreasonable.
19. **Debarment.** Akorn and Customer represent that they have not been debarred under 21 U.S.C. 335a or convicted of a felony for conduct relating to the regulation or handling of any drug product and will not use in any capacity in the performance of this Agreement or any Work Order the Services of any person or entity currently or ever debarred under 21 U.S.C. 335a or convicted of a felony for conduct relating to the regulation or handling of any drug product
20. **Amendments.** This Agreement may only be amended by a written agreement duly executed by both Parties.
21. **Force Majeure.** The period for which performance (other than the payment of money) is required by a Party shall be extended by the period during which such Party is unable to perform due to strikes, acts of God, war, shortages or unavailability of supplies, or other causes beyond the Party's reasonable control.
22. **Choice of Law.** This Agreement shall be construed and enforced according to the laws of the State of ~~Illinois~~ *New York*.
23. **Waiver.** The waiver by any Party of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach.
24. **Recitals.** The Recitals are an integral part of this Agreement.
25. **Headings.** The headings of the Sections or paragraphs of this Agreement are included for convenience only and shall not affect the meaning of this Agreement.
26. **Binding Effect.** This Agreement shall be binding upon the successors and assigns of the Parties.

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the date first above written.

FERA PHARMACEUTICALS, LLC

By: _____

Name: _____

Title: _____

Janet Della Fera
Janet L Della Fera
Chairperson

AKORN, INC.

By: _____

Name: Sean Brynjelsen

Title: Director, BD and Contract Manufacturing

Sean Brynjelsen

AKORN, INC.

By: _____

Name: Joe Bonaccorsi

Title: General Counsel, Sr. Vice President

Joe Bonaccorsi

AKORN, INC.

By: _____

Name: Tim Dick

Title: CFO and Senior Vice President

Tim Dick

EXHIBIT A**PRODUCT LIST**

PRODUCT DESCRIPTION	UNIT	PRODUCT PRICE	Exclusivity/Semi-Exclusivity
Neo-Poly-Dex	3.5 gram tube	\$2.99/tube	Exclusive
Baci-Poly	3.5 gram tube	\$2.99/tube	Semi-exclusive
Neo-Poly-Baci	3.5 gram tube	\$1.99/tube	Semi-exclusive
Gentamicin Ointment	3.5 gram tube	\$3.25/tube	Semi-exclusive
Bacitracin Ointment	3.5 gram tube	\$1.99/tube	Exclusive
Neo-Poly-Bac-HC Ointment	3.5 gram tube	\$3.25/tube	Exclusive
Erythromycin Ointment	3.5 gram tube	\$1.75/tube	Exclusive
Erythromycin Ointment	1 gram tube x 50	TBD	Exclusive

*Erythromycin 3.5 gram is Exclusive if based on Fera Pharmaceuticals approved regulatory filing. Akorn agrees not to utilize information contained in the Fera Pharmaceuticals regulatory filing for purposes of manufacturing said product including API source. However, nothing in this agreement prevents Akorn from using their existing FDA approval to manufacture, sell and distribute Erythromycin 3.5 gram.

EXHIBIT B

SPECIFICATIONS

Akorn to Provide for Semi-Exclusive Products

Fera to Provide for Exclusive Products

EXHIBIT C

ACTIVITIES TO COMMERCIALIZATION
FOR EACH EXCLUSIVE PRODUCT

1. Order raw materials and put in place material specifications
2. Perform USP method verifications
3. Generate Master Batch Record
4. Produce Exhibit Batch to Support Regulatory Filing

Assumptions:

- Customer agrees that no development work will be performed. Methods and manufacturing procedures will be followed as described in the respective technical package or ANDA.
- If additional activities are needed, which are not specified on original contract, customer will be notified of activity and will be billed separately.
- Outside Lab testing will be billed separately at cost + 10%.
- Customer will be responsible for purchase of any equipment that is project specific (tank, filler pumps, weighing scale, etc.). Customer will own associated equipment.
- Customer will be responsible for cost of dedicated disposables (e.g. HPLC columns)

EXHIBIT D**MINIMUM PURCHASE QUANTITIES**

Contract Year[*]	Minimum Purchase Quantities in Aggregate
1	100,000
2	500,000
3	500,000
4	500,000
5	500,000
6	500,000
7	500,000

* "Contract Year" means that twelve month period beginning with the Effective Date or an anniversary of the Effective Date.

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